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CASE CV0293

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

John M. Kilcoyne	John M. Kilcoyne	December 12, 2003
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Bhaskar et al.

APPLICATION NO: 09/661,971

FILED: September 14, 2000

FOR: Centrifuge Apparatus and Method with Improved Temperature Control

Art Unit: 1723

Examiner: K. Menon

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the Final Rejection of claims 1-9 and 16-18 in this application.

This Brief is submitted in triplicate as required, and is accompanied by the requisite fee of $330.00. Please charge the fee to Deposit Account No. 02-3869. No additional fee is believed to be necessary. However, if this fee is incorrect, or if any additional fee is required, please charge any fees due, or credit any overpayment, to Deposit Account No.02-3869.

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(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Bristol-Myers Squibb Company, a Delaware corporation, having a place of business at 345 Park Avenue, New York, NY 10154. Bristol-Myers Squibb Company is the assignee and owner of the entire interest in the above-identified application by virtue of an assignment which was recorded in the United States Patent and Trademark Office on June 28, 2000, at Reel/Frame 010929/0350.

(2) RELATED APPEALS AND INTERFERENCES

The undersigned knows of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

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Claims 1-9 and 16-18 are pending in this application.

Claims 1-9 and 16-18 stand rejected under 35 USC §103 as being unpatentable over (i) WO 98/30304 ("WO '304") in view of US Patent No. 5,073,012 ("Lynam"), and over (ii) WO '304 in view of US Patent No. 5,593,823 ("Wollowitz et al.").

No claims are allowed.

Appendix A annexed hereto contains a copy of the claims involved in the appeal. The appealed claims are claims 1-9 and 16-18.

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Appellants appeal the decision dated June 10, 2003, of the Primary Examiner finally rejecting claims 1-9 and 16-18. An Amendment After Final Rejection was filed on September 10, 2003, canceling claims 10-15. This amendment was entered. Accordingly, the claims stand as amended on September 10, 2003.

(5) SUMMARY OF INVENTION

The present invention relates to an apparatus and method for centrifuging and monitoring/controlling the temperature of a liquid, *e.g.*, blood or plasma, within a rotating centrifuge container without degradation of components of the liquid.

(6) ISSUES

The issues on appeal are whether claims 1-9 and 16-18 are patentable under 35 USC §103 over (i) WO 98/30304 ("WO '304") in view of US Patent No. 5,073,012 ("Lynam"), and over (ii) WO '304 in view of US Patent No. 5,593,823 ("Wollowitz et al.").

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Appellants submit that each of the rejected claims is separately patentable. However, for purposes of this appeal, appellants understand that the claims will stand or fall together.

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I. Claims 1-9 and 16-18 are patentable under 35 USC §103 over (i) WO 98/30304 ("WO '304") in view of US Patent No. 5,073,012 ("Lynam") and over (ii) WO '304 in view of US Patent No. 5,593,823 ("Wollowitz et al.").

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The inventors have discovered that while heating the blood or plasma in the manner described in WO '304 is advantageous, it can result in the degradation of proteins contained in the blood. In WO '304, heat is applied to container 10 at the initial stages of the process in order to raise the temperature of the blood or plasma to about 37°C prior to separation of plasma from the red blood cells, and halogen lamp 26 is preferably utilized to do so. Halogen lamp 26, however, may emit radiation in a wavelength range which will contact the blood or plasma in container 10 and potentially degrade key proteins therein. This wavelength range is from 190 to 400 nm which generally corresponds to the ultraviolet wavelength band of the electromagnetic spectrum.

In the present claimed invention, in order to avoid this potential degradation of blood proteins, filter 40 is provided between halogen lamp 26 and container 10, and in addition to any UV filtering that might occur if a polycarbonate material is used as the wall of the container. Filter 40 blocks all or substantially all of the radiation in the above mentioned wavelength range which is believed to be responsible for the unwanted protein degradation.

It is acknowledged in the final rejection that WO '304 does not teach or suggest the use of a filter disposed between the heat-emitting device and the container to filter the radiation emitted from the heat-emitting device to remove substantially all radiation therefrom having a wavelength in the range of from 190 to 400 nm, as presently claimed.

In this regard, the Examiner relies upon Lynam or Wollowitz. However, Appellants respectfully submit that neither Lynam nor Wollowitz rectify the deficiencies noted above in WO '304, and, more importantly, neither provides motivation to modify the teachings of WO '304 to include a filter as presently claimed.

Lynam is directed to a laminate electro-optic vehicular rearview mirror which is protected against scattering of glass or other mirror element fragments if broken or damaged in a collision while reducing the risk of laceration from contact with the front glass or other element. Lynam simply teaches that commercial polymers absorb ultraviolet radiation because they possess chromophoric groups either as regular constituents or as impurities. Lynam further teaches that, in this regard, chromophores which absorb electromagnetic radiation of a wavelength below about 400 nm are, therefore, effective screens against UV radiation, and polycarbonate, polyester and aromatic polyurethanes contain such chromophores as a major part of their structure.

It is asserted in the final rejection that Lynam is cited only to show that polycarbonate material filters UV radiation. However, Lynam goes on to say: "Yet, these above materials [including polycarbonate] do not absorb UV radiation uniformly over the entire UV range." (See Lynam, col. 8, lines 66-68.)

Wollowitz is directed to inactivating pathogens in blood. Rather than removing substantially all radiation having a wavelength in the range of from 190 to 400 nm, Wollowitz actually teaches a photoactivation device that employs UV radiation. See Wollowitz beginning on col. 8, line 55.

Neither Lynam nor Wollowitz suggests modifying the apparatus taught by WO '304 to include a filter located between the heat-emitting device and the container for filtering the radiation emitted from the heat-emitting device to remove substantially all radiation therefrom having a wavelength in the range from 190 to 400 nm. **Moreover, WO '304 suggests no need for it.** Appellants respectfully submit that the rejection is based upon a hindsight modification of the teachings of the primary reference, WO '304, using Appellants' specification because only Appellants' specification provides for an apparatus including a separate filter for centrifuging blood or plasma to separate a component therefrom without degradation of protein contained in the blood or plasma, as recited in the present claims.

There is still no suggestion other than Appellants' own specification of modifying the apparatus and method of WO '304, as presently claimed, to include a separate filter for radiation in the 190 to 400 nm wavelength range. Accordingly, this rejection should be reversed.

Further, the data in the application appears to be misread in the final rejection. The undersigned does not understand the criticism in the rejection of the data. For example, the

rejection asserts that "3/6 pairs show an increase in % FPB with UV filter." However, it appears to the undersigned that all sample pairs except sample pairs 9 and 10 show an increase with the filter. Additionally, pairs 9/10, 11/12 and 13/14 contain added thrombin. Again, all sample pairs except sample pairs 9 and 10 show an increase with the UV filter. Accordingly, it is submitted that this data rebuts any possible *prima facie* obviousness rejection.

For all these reasons, appellants believe that these rejections should be reversed.

II. Conclusion

For the reasons set forth herein, it is urged that the rejections of claims 1-9 and 16-18 should be reversed. Allowance of this application with claims 1-9 and 16-18 is in order. Such action is earnestly solicited.

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John M. Kilcoyne
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Date: December 12, 2003

APPENDIX

1. (Original) An apparatus for centrifuging blood or plasma to separate a component therefrom without degradation of protein contained in the blood or protein, comprising:

a container for holding the blood or plasma during the centrifuging;

a means for rotating the container;

a heat-emitting device provided opposite the container for radiating the blood or plasma in the container to increase the temperature of the blood or plasma; and

a filter disposed between the heat-emitting device and the container for filtering the radiation emitted from the heat-emitting device to remove substantially all radiation therefrom having a wavelength in the range of from 190 to 400 nm.

2. (Original) The apparatus according to Claim 1, wherein the container comprises a cylindrical member, a piston diplaceable therein, a top wall and a tubular piston rod extending through the top wall, the piston rod dividing the cylindrical member into a first chamber located above the piston between the piston and the top wall, and a second chamber positioned below the piston.

3. (Original) The apparatus according to Claim 2, further comprising a piston activating mechanism connected to the piston for moving the piston from a first position in the cylindrical member to a second position in the cylindrical member.

4. (Original) The apparatus according to Claim 1, wherein the means for rotating the container comprises a supporting turntable with means for releasably retaining the container, and a motor coupled to the supporting turntable, the motor rotating the supporting turntable and the container about a central axis thereof.

5. (Original) The apparatus according to Claim 1, wherein the heat-emitting device comprises a first heating source for emitting visible light substantially directed towards the container.

6. (Original) The apparatus according to Claim 5, wherein the first heating source is a halogen bulb.

7. (Original) The apparatus according to Claim 5, further comprising a second heating source for emitting infrared radiation substantially directed towards the container.

8. (Original) The apparatus according to Claim 7, wherein the second heating source comprises a metal heating plate.

9. (Original) The apparatus according to Claim 1, further comprising a first temperature sensor for detecting the temperature of air in an area around the container, a second temperature sensor for detecting the temperature of a surface of the container, and a control unit for controlling the heat-emitting device in response to the temperatures detected in the first and second temperature sensors.

16. (Original) A method for centrifuging blood or plasma to separate a component of the blood or plasma without degradation of protein contained in the blood or plasma, comprising the steps of:

heating the blood or plasma to about 36 to 37°C with radiation from a heat-emitting device;

filtering the radiation emitted from the heat-emitting device to remove substantially all radiation therefrom having a wavelength in the range of from 190 to 400 nm; and

centrifuging the blood or plasma.

17. (Original) The method according to Claim 16, wherein the sample of blood or plasma is heated to about 36°C.

18. (Original) The method according to Claim 17, wherein radiation having a wavelength in the range of from abut 190 to 400 nm is filtered from the radiation emitted by the heat-emitting device.

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